**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**CHARLESTON DIVISION**

**KAREN M. HEMBREE & KENNETH D. HEMBREE,**

**Plaintiffs,**

**v.** **Civil Action No. 2:14-cv-00912**

**BOSTON SCIENTIFIC CORP.,**

**Defendant.**

**MEMORANDUM OPINION AND ORDER**
**(*Defendant's Motion for Summary Judgment*)**

Pending before the court is defendant Boston Scientific Corporation's ("BSC") Motion for Summary Judgment against Plaintiffs Karen M. Hembree and Kenneth David Hembree [Docket 42]. As set forth below, BSC's Motion for Summary Judgment is **GRANTED IN PART** with respect to Ms. Hembree's claims for strict liability for manufacturing defect, strict liability for design defect, strict liability for failure to warn, negligent failure to warn, negligent manufacturing, breach of express warranty, breach of implied warranty of fitness for a particular purpose, breach of implied warranty of merchantability, and fraudulent concealment. BSC's Motion for Summary Judgment is **DENIED IN PART** with respect to Ms. Hembree's claims for negligent design, and Mr. Hembree's claim for loss of consortium.

## I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than

70,000 cases currently pending, approximately 15,000 of which are in the BSC MDL, MDL 2326. In an effort to efficiently and effectively manage this massive MDL, I decided to conduct pretrial discovery and motions practice on an individualized basis so that once a case is trial-ready (that is, after the court has ruled on all *Daubert* motions and summary judgment motions, among other things), it can then be promptly transferred or remanded to the appropriate district for trial. To this end, I ordered the plaintiffs and defendant to each select 50 cases, which would then become part of a "wave" of cases to be prepared for trial and, if necessary, remanded. (*See* Pretrial Order # 65, *In re: Boston Scientific Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-002326, entered Dec. 19, 2013, *available at* http://www.wvsd.uscourts.gov/MDL/boston/orders.html). This selection process was completed twice, creating two waves of 100 cases, Wave 1 and Wave 2. Ms. Hembree's case was selected as a Wave 2 case by the plaintiffs.

Ms. Hembree was surgically implanted with the Obtryx Transobturator Mid-Urethral Sling System (the "Obtryx") on December 14, 2011. (BSC's Mot. for Summ. J. & Mem. in Supp. ("Mem. in Supp.") [Docket 42], at 2). Dr. Phillip Solomon performed the surgery at a hospital in Charlotte, North Carolina. (*Id.*). Ms. Hembree claims that as a result of implantation of the Obtryx, she has experienced multiple complications including mesh erosion, mesh extrusion, vaginal pain, dyspareunia, pelvic pain, incomplete bladder emptying, and vaginal bleeding. (*See* Pl. Fact Sheet [Docket 42-8], at 6). She brings the following claims against BSC: strict liability for design defect, manufacturing defect, and failure to warn; negligence; breaches of express and implied warranties; fraudulent concealment; and punitive damages. (Short Form Compl. [Docket 42-1], at 4–5). Mr. Hembree brings a claim for loss of consortium. (*Id.*). In the instant motion, BSC moves for summary judgment on the grounds that "[p]laintiffs' legal theories are without evidentiary or legal support." (Mem. in Supp. [Docket 42], at 1).

## II. Legal Standards

### A. Summary Judgment

To obtain summary judgment, the moving party must show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not "weigh the evidence and determine the truth of the matter." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some "concrete evidence from which a reasonable juror could return a verdict in his [or her] favor." *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere "scintilla of evidence" in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Dash v. Mayweather*, 731 F.3d 303, 311 (4th Cir. 2013); *Stone v. Liberty Mut. Ins. Co.*, 105 F.3d 188, 191 (4th Cir. 1997).

### B. Choice of Law

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases such as this. The choice of law for these pretrial motions depends on whether they involve federal

or state law. "When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation." *In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted). In cases based on diversity jurisdiction, the choice-of-law rules to be used are those of the states where the actions were originally filed. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996) ("Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied."); *In re Air Crash Disaster Near Chi., Ill.*, 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2010 WL 2102330, at *7 (S.D. W. Va. May 25, 2010).

If a plaintiff files her claim directly into the MDL in the Southern District of West Virginia, however, as the Hembrees did in this case, I consult the choice-of-law rules of the state in which the plaintiff was implanted with the product. *See Sanchez v. Boston Scientific Corp.*, 2:12-cv-05762, 2014 WL 202787, at *4 (S.D. W. Va. Jan. 17, 2014) ("For cases that originate elsewhere and are directly filed into the MDL, I will follow the better-reasoned authority that applies the choice-of-law rules of the originating jurisdiction, which in our case is the state in which the plaintiff was implanted with the product."). Ms. Hembree received the Obtryx implantation surgery in North Carolina. Thus, the choice-of-law principles of North Carolina guide this court's choice-of-law analysis.

The parties agree, as does this court, that these principles compel application of North Carolina law. For tort claims, North Carolina generally applies the *lex loci delicti* approach, which

provides that "the state where the injury occurred is considered the situs of the claim." *Harco Nat'l Ins. Co. v. Grant Thornton LLP*, 698 S.E.2d 719, 722–23 (N.C. Ct. App. 2010). Here, the alleged injury occurred in North Carolina, where Ms. Hembree was implanted with the allegedly defective device. Thus, I apply North Carolina's substantive law to the tort claims in this case. For warranty claims, North Carolina applies the "most significant relationship" approach, which "requires the forum to determine which state has the most significant relationship to the case." *Boudreau v. Baughman*, 368 S.E.2d 849, 853–54 (N.C. 1988). North Carolina courts have found that "the place of sale, distribution, delivery, and use of the product, as well as the place of injury . . . to be the state with the most significant relationship to the warranty claims." *Id.* at 855–56. Thus, I also apply North Carolina's substantive law to the warranty claims in this case.

**III. Analysis**

BSC argues that it is entitled to summary judgment in this case because Ms. Hembree's claims lack either evidentiary or legal support. Ms. Hembree agrees that this court should dismiss her claims for strict products liability, negligent manufacturing, breach of express warranty, breach of implied warranty for a particular purpose, and breach of implied warranty of merchantability. (Pls.' Resp. in Opp'n to BSC's Mot. for Summ. J. ("Resp.") [Docket 66], at 1 n.1). Therefore, BSC's Motion for Summary Judgment on Ms. Hembree's claims for strict products liability, negligent manufacturing, breach of express warranty, breach of implied warranty for a particular purpose, and breach of implied warranty of merchantability is **GRANTED**. Below, I apply the summary judgment standard to each remaining claim.

**A. Negligent Failure to Warn**

Under North Carolina law, "[n]o manufacturer . . . shall be held liable in any product liability action for a claim based upon inadequate warning or instruction unless the claimant" can

satisfy three requirements. N.C. Gen. Stat. § 99B-5(a). First, the claimant must establish "that the manufacturer . . . acted unreasonably in failing to provide such warning or instruction." *Id.* Second, the claimant must establish "that the failure to provide adequate warning or instruction was a proximate cause of the harm for which damages are sought." *Id.* Finally, the claimant must establish either of the following:

> (1) At the time the product left the control of the manufacturer . . . , the product, without an adequate warning or instruction, created an unreasonably dangerous condition that the manufacturer . . . knew, or in the exercise of ordinary care should have known, posed a substantial risk of harm to a reasonably foreseeable claimant[; or] (2) After the product left the control of the manufacturer . . . , the manufacturer or seller became aware of or in the exercise of ordinary care should have known that the product posed a substantial risk of harm to a reasonably foreseeable user or consumer and failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances.

*Id.*

As a threshold matter, BSC argues that, under subsection (c) of the same statute, the learned intermediary doctrine shields it from liability. (Mem. in Supp. [Docket 42], at 7 (citing N.C. Gen. Stat. § 99B-5(c))). Subsection (c) provides: "[N]o manufacturer . . . shall be liable in a products liability action for failing to provide a warning or instruction directly to a consumer if an adequate warning or instruction has been provided to the physician or other legally authorized person who prescribes or dispenses that prescription drug for the claimant . . . ." N.C. Gen. Stat. § 99B-5(c).

While I am not persuaded that the plain language of subsection (c) provides the basis for application of the learned intermediary doctrine to the instant case, "[t]here are indications that North Carolina courts would adhere to the learned intermediary doctrine" in matters of product liability. *Baraukas v. Danek Med., Inc.*, No. 6:97CV00613, 2000 WL 223508, at *4 (M.D.N.C. Jan. 13, 2000) (citing *Foyle ex rel. McMillan v. Lederle Labs.*, 674 F. Supp. 530, 535–36 (E.D.N.C. 1987)). In fact, in *Baraukas*, the United States District Court for the Middle District of North

Carolina determined that the learned intermediary doctrine applied where the manufacturer warned the plaintiff's physician about bone screws. *Id.* Accordingly, consistent with the courts that have addressed this issue before me, I assess Ms. Hembree's negligent failure to warn claim under the learned intermediary doctrine.

Fatal to Ms. Hembree's failure to warn claim, Dr. Solomon, the implanting physician, did not rely on the Obtryx DFU in prescribing the device. (*See* Solomon Dep. [Docket 42-4], at 42:11–42:20) ("I've not—not seen the DFU . . . . I've not seen this document before."). Critically, a physician's failure to rely on a product's DFU may preclude a finding of causation. *See, e.g.*, *Lewis v. Ethicon, Inc.*, No. 2:12-CV-4301, 2014 WL 186869, at *4 (S.D. W. Va. Jan. 15, 2014) ("Although [the implanting physician] read the [DFU] at one time, she *admits* that she did not rely on it when she prescribed the TVT for [the plaintiff].") (emphasis added). This is because "[i]t is mere speculation that [the physician] would have learned of changes to the [D]FU without reading it." *Id.*; *see also Jones v. C. R. Bard, Inc.*, No. 2:11-CV-00114, 2013 WL 5591948, at *6 (S.D. W. Va. June 4, 2013) ("Simply put, because Dr. Williams did not review the IFU, no amount of warnings contained in it would have caused Dr. Williams to act any differently."). Here, the record is void of any evidence that would permit a reasonable juror to infer that Dr. Solomon read or relied on the Obtryx DFU in prescribing the device to Ms. Hembree. Accordingly, a reasonable juror could not infer that BSC's allegedly defective warnings proximately caused Ms. Hembree's injuries.[1]

Therefore, BSC's Motion for Summary Judgment on Ms. Hembree's negligent failure to warn claim is **GRANTED**.

[1] For this reason, I need not address the adequacy of the warning provided.

**B. Negligent Design**

Under North Carolina law, a plaintiff alleging inadequate design first must prove "that at the time of its manufacture the manufacturer acted unreasonably in designing or formulating the product, [and] that this conduct was a proximate cause of the harm for which damages are sought . . . ." N.C. Gen. Stat. § 99B-6(a). To determine whether BSC acted unreasonably in designing the Obtryx, North Carolina requires that "the factors to be considered . . . include, but are not limited to, the following":

> (1) The nature and magnitude of the risks of harm associated with the design or formulation in light of the intended and reasonably foreseeable uses, modifications, or alterations of the product[;] (2) The likely awareness of product users, whether based on warnings, general knowledge, or otherwise, of those risks of harm[;] (3) The extent to which the design or formulation conformed to any applicable government standard that was in effect when the product left the control of its manufacturer[;] (4) The extent to which the labeling for a prescription or nonprescription drug approved by the United States Food and Drug Administration conformed to any applicable government or private standard that was in effect when the product left the control of its manufacturer[;] (5) The utility of the product, including the performance, safety, and other advantages associated with that design or formulation[;] (6) The technical, economic, and practical feasibility of using an alternative design or formulation at the time of manufacture[;] (7) The nature and magnitude of any foreseeable risks associated with the alternative design or formulation.

*Id.* § 99B-6(b). Additionally, a plaintiff must prove one of the following:

> (1) At the time the product left the control of the manufacturer, the manufacturer unreasonably failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design or formulation that could then have been reasonably adopted and that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product[; or] (2) At the time the product left the control of the manufacturer, the design or formulation of the product was so unreasonable that a reasonable person, aware of the relevant facts, would not use or consume a product of this design.

*Id.* § 99B-6(a).

Here, genuine disputes of material fact exist with regard to: (1) whether BSC acted unreasonably in designing the Obtryx, *see id.* § 99B-6(a); and (2) whether BSC unreasonably failed

to adopt a safer, practical, feasible, and otherwise reasonable alternative design, *see id.* § 99B-6(a)(1), or whether the design or formulation of the product was so unreasonable that a reasonable person, aware of the relevant facts, would not use it.[2] *See id.* § 99B-6(a)(2).

Therefore, BSC's Motion for Summary Judgment on Ms. Hembree's negligent design claim is **DENIED**.

**C. Fraudulent Concealment**

Ms. Hembree's Short Form Complaint raises fraudulent concealment only as a safeguard to toll the statute of limitations. (Short Form Compl. [Docket 42-1], at 5 ("Count VIII – Discovery Rule, Tolling and Fraudulent Concealment")). Likewise, the Master Complaint does not discuss fraudulent concealment independent of the statute of limitations. Accordingly, to the extent a fraudulent concealment claim has been raised at the summary judgment stage, BSC's Motion for Summary Judgment on Ms. Hembree's fraudulent concealment claim is **GRANTED.**

**D. Loss of Consortium**

BSC contends that it is entitled to summary judgment on Mr. Hembree's loss of consortium claim because loss of consortium is a derivative claim that cannot survive without Ms. Hembree's claims. While an accurate statement of the law, because Ms. Hembree's claim for negligent design survives summary judgment, so does Mr. Hembree's loss of consortium claim. BSC's Motion for Summary Judgment on this claim is **DENIED**.

[2] BSC argues that the fact that BSC received FDA clearance for its products forecloses the possibility that a reasonable juror could determine that BSC acted unreasonably in designing the Obtryx. As I have previously held, however, 510(k) clearance from the FDA is not relevant to state tort law. *See, e.g.*, *Sanchez v. Boston Scientific Corp.*, 38 F. Supp. 3d 727, 744 (S.D. W. Va. 2014) ("Evidence regarding the 510(k) process poses a substantial risk of misleading the jury and confusing the issues. That a device has been given clearance through the FDA's 510(k) process is not relevant to state tort law."); *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 753–56 (S.D. W. Va. 2014) (same).

**IV. Conclusion**

For the reasons discussed above, it is **ORDERED** that BSC's Motion [Docket 42] be **GRANTED IN PART** with respect to Ms. Hembree's claims for strict liability for manufacturing defect, strict liability for design defect, strict liability for failure to warn, negligent failure to warn, negligent manufacturing, breach of express warranty, breach of implied warranty of fitness for a particular purpose, breach of implied warranty of merchantability, and fraudulent concealment, and **DENIED IN PART** with respect to Ms. Hembree's claim of negligent design, and Mr. Hembree's claim for loss of consortium.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: May 7, 2015

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE